Docusign Envelope ID: 468F86FA-23E7-4CF1-B33B-C99D1B0B8B50

Patient Information Leaflet

S4

PROPRIETARY NAME AND DOSAGE FORM:

FEIBA® 500 U

FEIBA® 1 000 U

(Powder and solvent for solution for injection Factor VIII Inhibitor Bypassing Activity)

Descriptive Name of Medicine:

Anti-Inhibitor-Coagulant Complex

Steam Treated

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Read all of this leaflet carefully before you are given FEIBA

• Keep this leaflet. You may need to read it again.

• If you have further questions, please ask your doctor or pharmacist.

• FEIBA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What FEIBA is and what it is used for

2. What you need to know before you use FEIBA

3. How to use FEIBA

4. Possible side effects

5. How to store FEIBA

6. Contents of the pack and other information

1. WHAT FEIBA is and what it is used for

FEIBA is a preparation made from human plasma which allows haemostasis, even when individual coagulation factors are reduced or lacking.

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FEIBA 500 U

The active substance per rubber-capped vial is 500 units Factor VIII inhibitor bypassing activity as contained in 200 – 600 mg human plasma protein.

FEIBA 1 000 U

The active substance per rubber-capped vial is 1 000 units Factor VIII inhibitor bypassing activity as contained in 400 – 1 200 mg human plasma protein.

FEIBA also contains factors II, IX and X, mainly in non-activated form as well as activated factor VII. Factor VIII coagulant antigen (F VIII C:Ag) and the factors of the kallikrein-kinin system are present only in trace amounts, if at all.

The other components are sodium chloride and sodium citrate.

Solvent

Sterilised Water for Injections

All plasma units are exclusively obtained from licensed blood banks and licensed plasmapheresis (a blood purification procedure used to treat several autoimmune diseases) centres in Europe and the United States of America. All blood donors are volunteers.

Each unit of plasma used for manufacture of FEIBA has been tested. To further reduce the potential risk of viral transmission, the product is steam treated under product-specific conditions.

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FEIBA is used:

• To treat spontaneous bleeding episodes in haemophilia A and haemophilia B patients with inhibitors

(haemophilia is when your blood does not clot properly)

• In haemophilia A and haemophilia B patients with inhibitors if they need surgery.

• In haemophilia A and haemophilia B patients with inhibitors to prevent frequent bleeding.

• To treat non-haemophiliacs who have developed antibodies in their blood that prevent factor VIII, IX and XII from working.

2. What you need to know before you use FEIBA

You should not be given FEIBA:

– In the following situations, your doctor will use FEIBA only if no therapeutic alternatives to FEIBA are available:

• If you are allergic (hypersensitive) to Factor VIII Inhibitor Bypassing Activity or any of the other ingredients of FEIBA.

• Disseminated intravascular coagulation (DIC) (disorder in which the proteins that control blood clotting become overactive and use up the blood's clotting factors, which can lead to massive bleeding in other places).

• Acute thrombosis (presence of a blood clot in a blood vessel) or embolism (an obstruction in a blood vessel due to a blood clot or other foreign matter that gets stuck while traveling through the bloodstream), or in heart attacks.

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Warnings and precautions

Talk to your doctor or healthcare professional before being given the injection.

Allergic-Type Hypersensitivity Reactions

Hypersensitivity reactions may occur, as is the case with all intravenously administered plasma products. To be able to recognize an allergic reaction as soon as possible, you should be aware of potential early symptoms of an allergic reaction such as

- redness of the skin
- skin rash
- nettle-rash (urticaria)
- itching
- swelling of lips and tongue
- breathing difficulties/dyspnoea
- wheezing
- tightness of the chest
- dizziness
- sudden drop of blood pressure (dizziness)

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If one or more of these symptoms occur, stop the infusion immediately and contact your doctor. The listed symptoms may be early indications of an anaphylactic shock, which is a severe and life-threatening allergic reaction. Severe symptoms require prompt emergency treatment.

Your doctor will only re-use FEIBA in patients with suspected allergy to the product or any of its components after careful weighing of the expected benefit and the risk of re-exposure and/or no reaction with another preventative therapy or alternative therapeutic agents is to be expected.

If you experience major changes in blood pressure or pulse rate, breathing difficulties, coughing or chest pain. Stop the infusion immediately and contact your doctor. Your doctor will initiate the appropriate diagnostic and therapeutic measures.

Single doses patients: You will be monitored for the development of Disseminated Intravascular Coagulation (blood clots form throughout the body, blocking small blood vessels), and/or symptoms of acute coronary ischaemia (insufficient supply of blood to an organ) and for symptoms of other thrombotic or thromboembolic events(presence of a blood clot in a blood vessel).

Non Haemophilic Patients

Non haemophilic patients with acquired inhibitors(restrainers) against factors VIII, IX or XII may have both a bleeding tendency and an increased risk of thrombosis (clotting of the blood in a part of the circulatory system) at the same time.

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Thromboembolic Events

Thromboembolic events which are conditions that arise from the blocking of a blood vessel by a blood clot may occur with the use of FEIBA. It is therefore important that your healthcare professional is aware if you have suffered a heart attack or have any condition that results in blood clots (e.g., DIC, venous thrombosis, embolisms, stroke).

If you are emicizumab exposed your doctor will monitor you closely.

Measures to prevent transmission of infectious medicines

When medicines are made from human blood or plasma, certain measures are put in place to prevent infections being passed on to patients. These include careful selection of blood and plasma donors to make sure those at risk of carrying infections are excluded, and the testing of each donation and pools of plasma for signs of virus/ infections.

Manufacturers of these products also include steps in the processing of the blood and plasma that can inactivate or remove viruses. Despite, when medicines prepared from human blood or plasma are administered, the possibility of passing on infection cannot be totally excluded. This also applies to unknown or emerging viruses or other types of infections.

The measures taken are considered effective for enveloped viruses such as HIV (virus which causes AIDS), hepatitis B virus and hepatitis C virus, and for the non-enveloped hepatitis A virus and parvovirus B19. Parvovirus B19 infection may be serious for pregnant women (foetal infection) and for individuals with immunodeficiency or increased erythropoiesis (the production of red blood cells) (e.g., haemolytic anaemia i.e., abnormal breakdown of red blood cells).

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Appropriate vaccination (hepatitis A and B) should be considered for patients in regular or repeated receipt of human plasma-derived products including FEIBA.

Discordant Response to Bypassing Medicines

Due to patient-specific factors the response to a bypassing medicine can vary, and in a given bleeding situation patients experiencing insufficient response to one medicine may respond to another medicine.

If insufficient response to one bypassing medicine occurs, use of another medicine should be considered.

Anamnestic Responses

If you have inhibitors administration of FEIBA may result in an initial rise in inhibitor levels. Upon continued administration of FEIBA, inhibitors may decrease over time.

Paediatric population

Case reports and limited clinical trial data suggest that FEIBA can be used in children younger than 6 years of age.

It is strongly recommended that every time you receive a dose of FEIBA the name and batch number of the product FEIBA are recorded in order to maintain a record of the batches use.

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Using other medicines with FEIBA:

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

• Tell your doctor if you are to be treated with FEIBA after you have received emicizumab (a

medicine used for treating patients with haemophilia A who have developed factor VIII

inhibitors). Your doctor will need to monitor you closely.

• The possibility of the blocking of a blood vessel by a blood clot may occur when systemic antifibrinolytics (medicines used to control mild bleeding episodes) such as tranexamic acid

and aminocaproic acid are used during treatment with FEIBA. If treatment with both medicines is necessary, an interval of at least 6 to 12 hours between the administration of the two medicines must be observed.

FEIBA should not be mixed with other medicines before administration, as the efficacy and tolerance of the preparation may be impaired.

It is advisable to rinse a common venous access with a saline solution before and after the administration of FEIBA.

Pregnancy and Breastfeeding:

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

The safety of FEIBA for use in pregnant or lactating women has not been established.

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• Your doctor will decide if FEIBA may be used during pregnancy and breast-feeding. Due to the increased risk of blood clotting during pregnancy, FEIBA should be administered only under careful medical supervision and only if clearly indicated.

Driving and Using machinery:

No effects on the ability to drive and use machines have been observed.

Excipient related considerations

FEIBA contains Sodium:

500 U

This medicine contains approximately 40 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 2% of the recommended maximum daily dietary intake of sodium for an adult.

1 000 U

This medicine contains approximately 80 mg sodium (main component of cooking/table salt) in each vial. This is equivalent to 4% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use FEIBA:

Always use FEIBA exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

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You will not be expected to give yourself FEIBA. It will be given to you by a person who is qualified to do so.

Your doctor will decide the dose you are to receive and for how long it will be given according to your bleeding rate and body weight.

If you have the impression that the effect of FEIBA is too strong or too weak, tell your doctor or pharmacist.

Reconstitute the freeze-dried FEIBA powder with the enclosed solvent and administer the solution intravenously.

Taking into consideration the severity of the blood coagulation disorder, the location and extent of the haemorrhage (bleed), and your general condition and response to the preparation, the doctor has determined the dose and dosage intervals required for you personally. Do not change the dosage established by your doctor and do not discontinue the application of the preparation independently.

Warm the product to room or body temperature prior to administration if necessary.

FEIBA is to be reconstituted only immediately before administration. The solution should then be used immediately (the preparation does not contain preservatives).

Swirl gently until all material is dissolved. Ensure that FEIBA is completely dissolved; otherwise, less FEIBA Units will pass through the device filter.

Solutions, which are turbid or have deposits are to be disposed of appropriately. Do not reuse opened containers.

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Use only the provided solvent (sterilized water for injections) and devices for reconstitution.

Do not use the product, if its sterile barrier system or its packaging is damaged or it shows any sign of deterioration.

Reconstitution of Concentrate for FEIBA : 500 U / 20 ml , 500 U / 10 ml and 1000 U / 20 ml

Use aseptic technique throughout entire procedure.

FEIBA may be reconstituted with either Transfer Needles or with the Baxject II Hi-Flow device

Transfer Needles

1. Warm the unopened vial containing the solvent (sterilised water for injections) to room

temperature, e.g., using a sterile water bath for warming within several minutes (max. +37°C) if necessary.

2. Remove protective caps from the concentrate vial and solvent vial (Fig. A) and clean the rubber

stoppers of both.

3. Remove protective covering from one end of the supplied transfer needle by twisting and pulling

(Fig. B). Insert the exposed needle through the rubber stopper of the solvent vial (Fig. C).

4. Remove protective covering from the other end of the transfer needle taking care not to touch the exposed end.

5. Invert the solvent vial over the concentrate vial, and insert the free end of the transfer needle

through the rubber stopper of the concentrate vial (Fig. D). The solvent will be drawn into the concentrate vial by vacuum.

6. Disconnect the two vials by removing the needle from the concentrate vial (Fig. E). Gently agitate

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or rotate the concentrate vial to accelerate dissolution.

7. Upon complete reconstitution of the concentrate, insert the enclosed aeration needle provided (Fig. F) and any foam will collapse. Remove aeration needle.

Injection/Infusion:

Use aseptic technique throughout entire procedure.

1. Remove protective covering from the supplied filter needle by twisting and pulling and fit the needle onto a sterile disposable syringe. Draw the solution into the syringe (Fig. G).

2. Disconnect the filter needle from the syringe and slowly inject the solution intravenously with the enclosed winged set for injection (or the enclosed disposable needle).

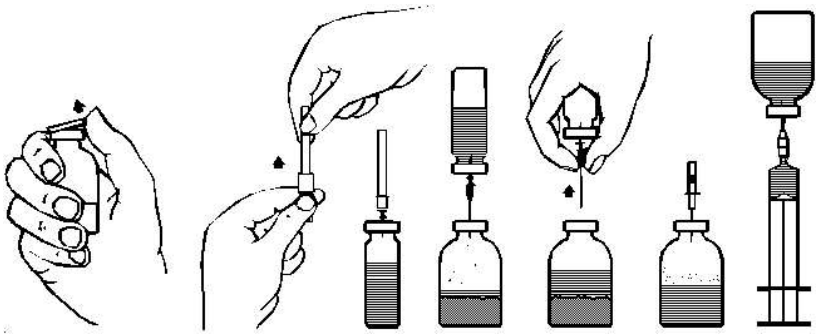


Fig.A Fig.B Fig.C Fig.D Fig.E Fig.F Fig.G

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Baxject II Hi-Flow

1. Warm the unopened vial containing the solvent (sterilised water for injections) to room temperature, e.g., using a sterile water bath for warming within several minutes (max. +37°C) if necessary.

2. Remove the protective caps from the FEIBA vial and solvent vial and cleanse the rubber stoppers of both. Place the vials on a flat surface.

3. Open the package of BAXJECT II Hi-Flow device by peeling away the paper lid without touching the inside (Fig. a). Do not remove the transfer device from the package.

4. Turn the package over and insert the clear plastic spike through the solvent stopper (Fig. b). Grip the package at its edge and pull the package off BAXJECT II Hi-Flow (Fig. c). Do not remove the blue cap from BAXJECT II Hi-Flow.

5. With the transfer device attached to the solvent vial, invert the system so that the solvent vial is on top of the device. Insert the purple plastic spike of BAXJECT II Hi-Flow through the FEIBA vial stopper. The vacuum will draw the solvent into the FEIBA vial (Fig. d).

6. Swirl, but do not shake, the entire system gently until all material is dissolved. Ensure that FEIBA is completely dissolved, otherwise active material will not pass through the device filter.

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Fig. a Fig. b Fig. c



Instructions for Injection/Infusion:

1. Remove the blue cap from BAXJECT II Hi-Flow. Tightly connect the syringe to BAXJECT II Hi-Flow. DO NOT DRAW AIR INTO THE SYRINGE. (Fig. e). In order to ensure tight connection between syringe and BAXJECT II Hi-Flow, the use of a luer lock syringe is highly recommended (turn syringe in clockwise direction until stop position when mounting).

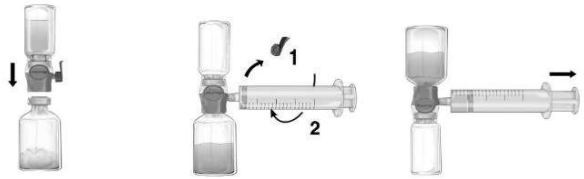
2. Invert the system so that the dissolved product is on top. Draw the FEIBA solution into the syringe by pulling the plunger back SLOWLY and ensure that the tight connection between BAXJECT II Hi-Flow and the syringe is maintained throughout the whole pulling process (Fig. f)

3. Disconnect the syringe.

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4. If foaming of the product in the syringe occurs, wait until the foam is collapsed. Slowly administer the solution intravenously with the enclosed infusion set (or a disposable needle).

Fig. d Fig. e Fig. f



Do not exceed an infusion rate of 2 U FEIBA/kg body weight in one minute.

Reconstitution of Concentrate for FEIBA: 500 U / 5 ml & 1000 U / 10ml

Use aseptic technique throughout entire procedure.

FEIBA may be reconstituted with either Transfer Needles or with the Baxject II Hi-Flow device

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Transfer Needles

1. Warm the unopened vial containing the solvent (sterilised water for injections) to room temperature, e.g., using a sterile water bath for warming within several minutes (max. +37°C) if necessary.

2. Remove protective caps from the concentrate vial and solvent vial (Fig. A) and clean the rubber stoppers of both.

3. Remove protective covering from one end of the supplied transfer needle by twisting and pulling (Fig. B). Insert the exposed needle through the rubber stopper of the solvent vial (Fig. C).

4. Remove protective covering from the other end of the transfer needle taking care not to touch the exposed end.

5. Invert the solvent vial over the concentrate vial, and insert the free end of the transfer needle through the rubber stopper of the concentrate vial (Fig. D). The solvent will be drawn into the concentrate vial by vacuum.

6. Disconnect the two vials by removing the needle from the concentrate vial (Fig. E). Gently agitate or rotate the concentrate vial to accelerate dissolution.

7. Upon complete reconstitution of the concentrate, insert the enclosed aeration needle provided (Fig. F) and any foam will collapse. Remove aeration needle.

Injection/Infusion:

Use aseptic technique throughout entire procedure.

1. Remove protective covering from the supplied filter needle by twisting and pulling and fit the

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needle onto a sterile disposable syringe. Draw the solution into the syringe (Fig. G).

2. Disconnect the filter needle from the syringe and slowly inject the solution intravenously with the enclosed winged set for injection (or the enclosed disposable needle).

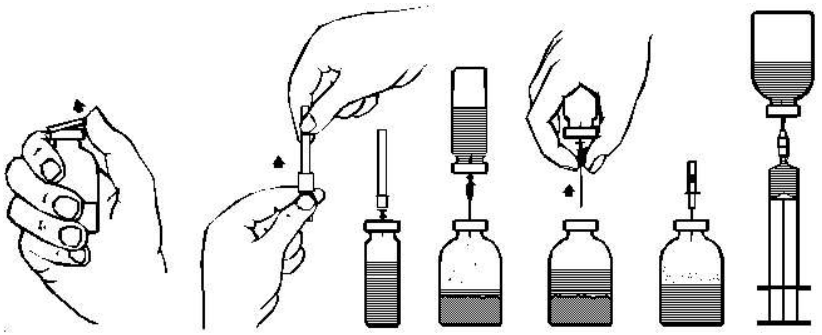


Fig.A Fig.B Fig.C Fig.D Fig.E Fig.F Fig.G

Baxject II Hi-Flow

1. Warm the unopened vial containing the solvent (sterilised water for injections) to room temperature, e.g., using a sterile water bath for warming within several minutes (max. +37°C) if necessary.

2. Remove the protective caps from the FEIBA vial and solvent vial and cleanse the rubber stoppers of both. Place the vials on a flat surface.

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3. Open the package of BAXJECT II Hi-Flow device by peeling away the paper lid without touching

the inside (Fig. a). Do not remove the transfer device from the package.

4. Turn the package over and insert the clear plastic spike through the solvent stopper (Fig. b). Grip the package at its edge and pull the package off BAXJECT II Hi-Flow (Fig. c). Do not remove the blue cap from BAXJECT II Hi-Flow.

5. With the transfer device attached to the solvent vial, invert the system so that the solvent vial is on top of the device. Insert the purple plastic spike of BAXJECT II Hi-Flow through the FEIBA vial stopper. The vacuum will draw the solvent into the FEIBA vial (Fig. d).

6. Swirl, but do not shake, the entire system gently until all material is dissolved. Ensure that FEIBA

is completely dissolved, otherwise active material will not pass through the device filter.

Fig. a Fig. b Fig. c



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Instructions for Injection/Infusion:

1. Remove the blue cap from BAXJECT II Hi-Flow. Tightly connect the syringe to BAXJECT II Hi-Flow. DO NOT DRAW AIR INTO THE SYRINGE. (Fig. e). In order to ensure tight connection between syringe and BAXJECT II Hi-Flow, the use of a luer lock syringe is highly recommended (turn syringe in clockwise direction until stop position when mounting).

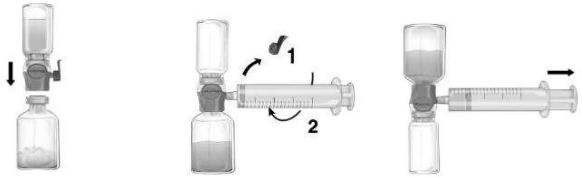
2. Invert the system so that the dissolved product is on top. Draw the FEIBA solution into the syringe by pulling the plunger back SLOWLY and ensure that the tight connection between BAXJECT II Hi-Flow and the syringe is maintained throughout the whole pulling process (Fig. f)

3. Disconnect the syringe.

4. If foaming of the product in the syringe occurs, wait until the foam is collapsed. Slowly administer the solution intravenously with the enclosed infusion set (or a disposable needle).

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Fig. d Fig. e Fig. f



Do not exceed an infusion rate of 10 U FEIBA/kg body weight per minute.

If devices other than those supplied with FEIBA are used, ensure use of an adequate filter with at least 149 µm pore size.

Document product administration on the enclosed self-adhesive label.

If you receive more FEIBA than you should:

Since a healthcare provider will administer this medicine, he/she will control the dosage. However, in the event of overdosage your doctor will manage the overdosage.

4. POSSIBLE SIDE EFFECTS

FEIBA can cause side effects

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Not all side effects reported for FEIBA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking FEIBA, please consult your healthcare provider for advice.

Common side effects (may affect up to 1 in 10 people):
Hypersensitivity, Headache, Dizziness, Hypotension, Rash, Hepatitis B surface antibody positive.

Side effects with unknown frequency (the frequency cannot be estimated on the basis of the available data):

Blood and lymphatic system disorders: Disseminated intravascular coagulation (condition in which blood clots form throughout the body), Increase of inhibitor titer

Immune system disorders: Anaphylactic reactions, Nettle-rash on the entire body (Urticaria)

Nervous system disorders: Feeling of numbness in the limbs (hypoesthesia), Abnormal or reduced sensation (Paraesthesia), Stroke (Thrombotic stroke, Embolic stroke), Sleepiness (Somnolence), Altered sense of taste (Dysgeusia)

Cardiac disorders: Heart attack (Myocardial infarction), Palpitation of the heart (Tachycardia)

Vascular disorders: Blood clot formation with flushing into the vessels (thromboembolic events, venous and arterial thrombosis), Increase of blood pressure (Hypertension), Flushing

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Respiratory, Thoracic, and Mediastinal disorders: Obstruction of the pulmonary artery (Pulmonary embolism), Constriction of the air passages (Bronchospasm), Wheezing, Cough, Breathlessness (Dyspnoea)

Gastrointestinal disorders: Vomiting, Diarrhoea, stomach discomfort, Feeling of sickness (Nausea)

Skin and subcutaneous tissue disorders: Feeling of numbness in the face, Swelling of face, tongue and lips (Angioedema), Nettle-rash on the entire body (Urticaria), Itching (Pruritus)

General disorders and complaints at the injection site: Pain at injection site, general feeling of being unwell, feeling hot, chills, fever, chest pain, chest discomfort

Investigations: Drop in blood pressure, increased levels of fibrin D-dimer in blood
Rapid intravenous infusion can cause stabbing pain and a sensation of numbness in face and limbs, as well as a decrease in blood pressure.

Myocardial infarctions (heart attack) were observed after the administration of doses above the maximum daily dose and/or prolonged application and/or the presence of risk factors for thromboembolism.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or health care provider. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Additionally, suspected adverse reactions can be reported to AE.southafricassa@takeda.com or on the 24 hours contact number: 082 525 3040. By reporting side effects, you can help provide more information on the safety of this.

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5. How to store FEIBA

Store all medicines out of reach of children.

Store at or below 25 °C. Do not freeze. Discard if frozen.

Store in the original package in order to protect from light.

FEIBA must not be used beyond the expiry date indicated.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What FEIBA contains:

Active substance: Factor VIII Inhibitor Bypassing Activity

FEIBA® 500 U:

1 ml contains 25 U* factor VIII inhibitor bypassing activity when reconstituted with 20 ml Water for Injections.

1 ml contains 50 U* factor VIII inhibitor bypassing activity when reconstituted with 10 ml Water for Injections.

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1 ml contains 100 U* factor VIII inhibitor bypassing activity when reconstituted with 5 ml Water for Injections.

FEIBA is presented as powder and solvent to prepare a solution for infusion containing 200 – 600 mg human plasma protein with a Factor Eight Inhibitor Bypassing Activity of 500 U* per vial.

FEIBA® 1 000 U:

1 ml contains 50 U* factor VIII inhibitor bypassing activity when reconstituted with 20 ml Water for Injections.

1 ml contains 100 U* factor VIII inhibitor bypassing activity when reconstituted with 10 ml Water for Injections.

FEIBA is presented as powder and solvent to prepare a solution for infusion containing 400 – 1 200 mg human plasma protein with a Factor Eight Inhibitor Bypassing Activity of 1 000 U* per vial.

List of excipients: sodium chloride, sodium citrate dihydrate, sterilised water for injections.

What Feiba looks like and the contents of the pack

Each pack of FEIBA contains:

One vial containing a lyophilized powder. It is a white to off-white or pale green powder or friable mass.

One vial containing a clear, colourless, aqueous solvent.

Kit for reconstitution and injection.

The reconstituted solution is colourless to slightly yellowish and clear to slightly turbid. It is essentially free from visible particles.

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PACKS

FEIBA 500 U + 5 ml Solvent
-R/C vial containing 500 FEIBA-units, lyophilized
-R/C vial containing 5 ml water for injections
-Kit for reconstitution and injection*

FEIBA 500 U + 10 ml Solvent

- R/C vial containing 500 FEIBA-units, lyophilized

- R/C vial containing 10 ml water for injections

- Kit for reconstitution and injection*

FEIBA 500 U + 20 ml Solvent

- R/C vial containing 500 FEIBA-units, lyophilized

- R/C vial containing 20 ml water for injections

- Kit for reconstitution and injection*

FEIBA 1 000 U + 10 ml Solvent
-R/C vial containing 1 000 FEIBA-units, lyophilized
-R/C vial containing 10 ml water for injections
-Kit for reconstitution and injection*

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FEIBA 1 000 U + 20 ml Solvent

- R/C vial containing 1 000 FEIBA-units, lyophilized

- R/C vial containing 20 ml water for injections

- Kit for reconstitution and injection*

*Kit for reconstitution and injection:

Transfer needles:

• Transfer needle (stainless steel, gamma-irradiated)

• Filter needle (stainless steel, gamma-irradiated)

• Disposable needle (hub and needle shield: PP, canula: stainless steel, ETO sterilizedresidual

ETO content: < 1 ppm)

• Butterfly needle (needle: stainless steel; tube: PVC; cap:PE; ETO sterilized-residual ETO content: < 1 ppm)

• Aeration needle (stainless steel, ETO sterilized-residual ETO content: < 1 ppm)

• Disposable syringe (PP, ETO sterilized-residual ETO content: < 1 ppm)

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Baxject II Hi-Flow:

• 1 BAXJECT II Hi-Flow for reconstitution

• 1 disposable syringe

• 1 disposable needle

• 1 butterfly needle

Not all pack sizes may be marketed.

Holder of Certificate of Registration

Takeda (Pty) Ltd

Building A, Monte Circle

64 Montecasino Boulevard

Fourways 2191

Gauteng, South Africa

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